



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0345]

Food and Drug Administration/National Institutes of Health/National Science Foundation Public Workshop on Computer Methods for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

Summary: The Food and Drug Administration (FDA) is announcing its fifth public workshop on Computer Methods for Medical Devices entitled “FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices.” The purpose of the workshop is to present, discuss, and receive input on an FDA library of models and data relevant to medical devices (day 1) and present, discuss, and receive input on a strategy to assess the credibility of computer models used to evaluate medical devices (day 2).

Dates and Times: The workshop will be held on June 11 and 12, 2013, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to:

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Persons: Donna Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3220, Silver Spring, MD 20993, 301-796-6309, Donna.Lochner@fda.hhs.gov; or Tina M. Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1272, Silver Spring, MD 20993, 301-796-6310, Tina.Morrison@fda.hhs.gov.

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on May 31, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. Select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan to register (301-796-5661 or Susan.Monahan@fda.hhs.gov). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (Susan.Monahan@fda.hhs.gov or 301-796-5661) no later than May 28, 2013.

Streaming Webcast of the Public Workshop: This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on May 31, 2013. Early registration is recommended because Webcast connections are limited.

Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 4, 2013. If you have never attended a Connect Pro event before, test your connection at

https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II of this document. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is July 10, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; i.e., animal, bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Nonproprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. Before substantial advances in the use of M&S for regulatory decision making can be attained, a strategy and consistent framework to assess the credibility of M&S is needed. Moreover, to foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to develop a strategy to scientifically assess the credibility of M&S and to develop a resource to publicize biomedical data, models and their validation for regulatory use.

II. Topics

Historically, M&S have been used as development and design optimization tools, rather than methods by which performance of final devices can be demonstrated. Further, modeling studies that are submitted to the Agency are supplemental and complement animal, bench and human testing provided in:

- Investigational Device Exemptions (investigational devices),
- 510(k) notifications (class II devices), and

- Pre-Market Approval applications (class III devices).

Some of the challenges with the current uses of M&S are:

- Reports typically lack sufficient details for adequate assessment because there are no reporting standards for computational modeling,
- Lack of sensitivity and uncertainty analyses for crucial input parameters, such as geometry, physical properties, boundary conditions,
- Lack of adequate validation to support the use of the computational model, and
- Lack of complete understanding of physiological loads and variations in patient populations.

Adequate verification and validation (V&V) are necessary in order to foster confidence and wider acceptance of M&S for use in medical device evaluation. Therefore, CDRH, in collaboration with the American Society of Mechanical Engineers, has been drafting a guide on the “Verification and Validation of Computational Modeling for Medical Devices.” The strategy is meant to create a framework for determining the risk associated with using a computational model in a specific context of use (COU) to inform decision making and for determining “how much” V&V is necessary to support the model for its COU. The two main components of this strategy are the Risk Assessment Matrix and the Credibility Assessment Matrix. Both of these tools will be presented and discussed at the workshop. Note that these tools are still in DRAFT format.

The workshop will also describe and discuss FDA’s efforts to create a resource or Library of biomedical data and models that can be used in regulatory applications. Key features and questions related to development of the Library and curation of data and models for the Library will be discussed. The goal of the FDA/NIH/NSF Workshop on Computer Modeling

and Validation for Medical Devices is to discuss and receive input on these tools to enhance their utility in the community.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07923 Filed 04/04/2013 at 8:45 am; Publication Date: 04/05/2013]